

## **ATTACHMENT B**

### **REMARKS**

By the present amendments, Claims 1, 5, 6, 7, 8 and 9 have been amended by canceling  $\beta$ -(1,3)-glucan like Laminarin, so that amended claims only cover oligo- $\beta$ -(1,3)-glucan. Claim 2 has been divided into amended claim 2 and new claim 10 in order to avoid the term "preferably". Claim 8 has been divided into amended claim 8 and new claim 11 in order to avoid the term "preferably". The minor objection to Claim 9 has also been overcome. All of these amendments are clearly supported in the specification and no new matter has been entered. Applicants submit that the present amendments and attachments overcome the outstanding rejections for the reasons as set forth below.

### **REJECTIONS UNDER 35 USC § 112 2<sup>ND</sup> PARAGRAPH**

Claims 1-3 and 5-8 were rejected under 35 USC 2<sup>nd</sup> paragraph for being indefinite.

These objections are no longer appropriate, since the terms "like" and "preferably" have been deleted from the respective claims.

### **REJECTIONS UNDER 35 USC § 112 1<sup>ST</sup> PARAGRAPH**

The Examiner objected that specification did not reasonably provide enablement for treating cancer comprising a monoclonal antibody with the oligo- $\beta$ -(1,3)-glucans presented in formula (1).

As indicated by Mr. Vaclav Vetvicka in the herewith attached "Declaration under Rule 132" in accordance with the test results communicated in the separate Test Report, the oligo- $\beta$ -(1,3)-glucans presented in formula (1) in combination with a monoclonal antibody are effectively efficient in the treatment of cancer.

Accordingly, Applicants submits that the application is sufficiently enabled.

### REJECTIONS UNDER 35 USC § 102

Claims 1-8 were rejected under 35 USC § 102 for being anticipated by Cheung (WO 02/058711).

This rejection, insofar as applied to the claims as amended, is respectfully traversed for reasons as stated below.

In fact, Cheung discloses a method of treating cancer comprising administering a composition comprising an effective amount of  $\beta$ -(1,3)-glucan and a monoclonal antibody. The  $\beta$ -(1,3)-glucans disclosed in this document are all poly-  $\beta$ -(1,3)-glucans (e.g. Barley glucan with molecular weights of 40-359K), whereas applicant's claims are limited to oligo-  $\beta$ -(1,3)-glucans, i.e., according to the IUPAC-IUBMB definition of oligosaccharides (see <http://www.chem.qmul.ac.uk/iupac/2carb/>), glucans with a defined structure as opposed to a polymer of unspecified length or a homologous mixture.

Accordingly, Applicants submit that the present claims 1-12 are novel in view of Cheung.

### REJECTIONS UNDER 35 USC § 103

Claims 1-9 were rejected for being obvious in view of Cheung and further in view of Tschmelitsch et al. This rejection, insofar as applied to the claims as amended, is respectfully traversed for reasons as stated below.

In addition to the disclosure of a method of treating cancer comprising administering a composition comprising an effective amount of  $\beta$ -(1,3)-glucan and a monoclonal antibody, Cheung teaches that high molecular weight (poly)- $\beta$ -(1,3)-glucans (e.g. Barley glucan with a molecular weight of 359K; p.23, l. 20-21) show a higher anti-tumor effect when administered in the presence of a monoclonal antibody than those with a lower molecular weight (e.g. 137K, p.23, l. 31).

Thus a person skilled in the art would never have expected that the low molecular weight oligo- $\beta$ -(1,3)-glucans would show any synergetic anti-tumor effect when administered in combination with a monoclonal antibody.

Tschmelitsch et al. teaches the enhanced anti-tumor activity of a combination a monoclonal antibody with chemotherapy.

The document does not teach the use of any glucan at all.

Therefore, a person skilled in the art would not have been able to deduce the therapeutic method claimed in the present application from Tschmelitsch et al..

Even when combining both of the cited references, the person skilled in the art would not have been able to deduce the method claimed in the present application. The main reason for this is that there is no hint in any of the documents on the use of an oligo- $\beta$ -(1,3)-glucan, which is one of the essential features of the present invention. Cheung even implies, that, in order to obtain a synergistic effect with monoclonal antibodies, it is important to use (poly)- $\beta$ -(1,3)-glucan presenting a high molecular weight. Cheung thus teaches away from the present claims, and it the invention would thus not have been obvious in light of the combination of Cheung and Tschmelitsch et al.

In view of the above, it is considered that all of the prior rejections have been overcome and that the application is now in condition for immediate allowance.

Favorable consideration and prompt allowance of these claims are respectfully requested.

**END OF REMARKS**